

Seminar title: e-Submission the quality review

Venue: Sharm Al Sheikh, Egypt

Time: 6-8 October 2012

Themes: This seminar is intended mainly for governmental authorities intending to migrate their paper based submission & review procedure to electronic submission & review of dossiers. Expert speakers from EMA, MHAR, AGES and German MOH will review their country experience in detail for such operation pointing the required planning, resource requirement and review process re-engineering.

Smooth system usage through gentle system utilization by the applicants is explained together with difficulties experienced in such projects.

Further the seminar will focus in particular on module 3 review as an example for the complete cycle of the review process. This will include review cycle management and process optimization. EiY will be used to demonstrate life the review process in addition the full technology aspects of EiY will be revealed.

The seminar will seek SFDA experience with eCTD implementation of EiY and will provide platform for experience exchange between attending delegates.

Further SFDA unique medical device electronic submission will be demonstrated and ruling guidelines explained.

The 3 days seminar is designed to use day 1 to review countries experiences in implementing eCTD review system including review life cycle management. Day 2 will be dedicated to brain storm implementation blue print plan for authorities intending to implement the eCTD review system and review life cycle management. The example to use is module 3 implementation. Day 3 is utilized to demonstrate full dossier preparation life cycle management using eCTDmanager followed by submission validation using SFDA validator. Private sector will be allowed to join day 3 only.